

#### **IV. REMARKS/ARGUMENTS**

The Specification has been amended to update the priority data of the present application.

##### **A. Status of Claims**

Claims 38 and 39 have been amended. Claims 40-45 have been cancelled without prejudice. New claims 48-50 have been added.

Support for new claim 48 is found, e.g., at page 12, lines 19-20 and support for new claims 49-50 is found, e.g., at page 11, lines 4-6. It is respectfully submitted that no new matter has been added to the application by virtue of the present amendment.

##### **B. Rejection under 35 U.S.C. 103 (a) over Baker et al., Swingle et al. and/or Rabasseda**

In the Office Action, the Examiner rejected claims 37-41, 43-44 and 46-47 under 35 U.S.C 103 (a) over US 4,569,937 (hereinafter “Baker et al.”), Swingle et al. Drugs Exptl. Clin. Res. Vol. X (8-9) (1984) (hereinafter “Swingle et al.”) and/or Rabasseda, Drugs of Today Vol. 32, No. 5 (1996) pages 365-384 (hereinafter “Rabasseda”). The Examiner stated that “it would have been prima facie obvious to one of ordinary skill in the art ... to modify the Baker reference analgesic composition by substituting the NSAID Nimesulide (for the NSAID ibuprofen) or supplementing Baker’s composition with Nimesulide in light of the benefits of Nimesulide ... as taught by the Swingle et al. and/or Rabasseda references.” Applicants note that claim 37 is not currently pending.

Initially, it is noted to the Examiner that the claims recite, in part, “an analgesic combination consisting essentially of nimesulide ... and oxycodone” (emphasis added). Therefore, the claims do not encompass an analgesic combination of three analgesics (e.g., nimesulide, oxycodone and ibuprofen). Accordingly, the Examiner’s rejection with respect to

“supplementing” Baker’s composition (i.e., a narcotic analgesic and ibuprofen) with nimesulide is not applicable to the pending claims.

Regarding the remainder of the rejection, it is initially noted that the purported invention of Baker et al. is directed to pharmaceutical compositions of narcotic analgesics and ibuprofen which “... exhibit unexpectedly enhanced analgesic activity ...” (See Abstract). Baker et al. is limited to combinations wherein the NSAID is ibuprofen and does not teach or suggest that the purported “unexpectedly enhanced analgesic activity” would occur with an NSAID which is different than ibuprofen.

Therefore, modifying the formulation of Baker et al. in view of Swingle et al. and/or Rabasseda, as proposed by the Examiner, by substituting ibuprofen with nimesulide would result in a dosage form which is not directed to the principle of operation described in Baker et al. (i.e., the purported synergism of narcotic analgesics and ibuprofen). The Examiner is reminded that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” See MPEP 8<sup>th</sup> edition, Revision 2, p.2100-132.

Therefore, it is respectfully requested that the 35 U.S.C. 103(a) rejection over Baker et al., Swingle et al. and/or Rabasseda be removed.

**C. Rejection under 35 U.S.C. 103 (a) over Baker et al., Swingle et al. and/or Rabasseda in view of Mayer et al.**

In the Office Action, the Examiner further rejected claims 38-44 and 46-47 under 35 U.S.C. 103 (a) over Baker et al., Swingle et al. and/or Rabasseda in view of US 5,834,479 (hereinafter “Mayer et al.”). The Examiner stated that the Mayer et al. is cited “[t]o the extent that the Baker, Swingle et al. and/or Rabasseda references fail to teach the administration of the analgesia active agent ... ‘before, ... with, or after’ administration of the oxycodone.”

This rejection is respectfully traversed. In view of the arguments presented above, it is respectfully submitted that the combination of Mayer et al., Swingle et al. and/or Rabasseda does not teach or suggest the present invention which is directed, in part, to “an analgesic combination consisting essentially of nimesulide ... and oxycodone ...” As Mayer et al. is relied upon by the Examiner solely for describing the administration of one agent “before, ... with, or after” the other agent, it is respectfully submitted that Mayer et al. does not cure the deficiencies of Baker et al., Swingle et al. and/or Rabasseda as discussed above.

Therefore, it is respectfully requested that 35 U.S.C. 103(a) rejection over Baker et al., Swingle et al. and/or Rabasseda in view of Mayer et al. be removed.

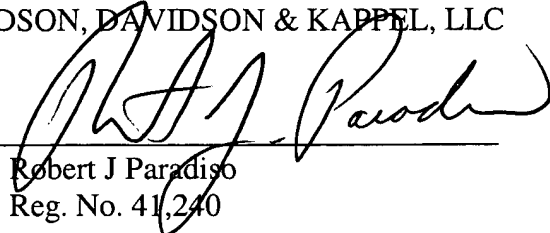
V. CONCLUSION

The present application is respectfully submitted as being in condition for allowance,  
and applicants respectfully request such action.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

  
Robert J Paradiso  
Reg. No. 41,240

DAVIDSON, DAVIDSON & KAPPEL, LLC  
Patents, Trademarks and Copyrights  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940